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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,329	11/09/2001	Michael Baudino	11738.00050	4048
27581	7590	04/18/2006	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			HAYES, MICHAEL J	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/053,329

Applicant(s)

BAUDINO ET AL.

Examiner

Michael J. Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86, 89-107 and 110-141 is/are pending in the application.
- 4a) Of the above claim(s) 1-79 and 110-141 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 80-86 and 89-107 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, at least one catheter port coupled to a first catheter and a second catheter configured to deliver at least two drugs as recited in claim 85 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 80-86, 89-102, and 104-105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe various limitations recited in the new claims 80-86, 91, 92, 93, and 104. It appears that these limitations are new matter: an implanted therapy delivery device that stores liquid agent and is coupled to first and second catheters as recited in claims 80, 81, and 103, the delivery device port coupling to first and second catheters as recited in claim 85, determining liquid infusion rate through first and second catheters with a parameter and signal level as recited in claim 91, use of a timer and adjusted parameter to control liquid agent delivery as recited in claims 92, 93, 94, increasing setting of infusion rate not exceeding a maximum value in response to excessive target activity as recited in claims 95-98, a second sensor to provide input to the processor for liquid delivery as recited in claim 99, a pump storing drug and connected to first and second catheters as recited in claim 102, and the sensor in the proximity of liquid delivery position as recited in claim 104.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 96 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 96 recites a setting exceeding a maximum value, but claim 96 depends from claim 95 which recites the setting does not exceed a maximum value. Claim 96 is inconsistent with claim 95. Correction is required.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis in the specification for setting maximum value as used in claims 95-98.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 80, 81, 82, 83, 85, 86, 89, 103, and 107 are rejected under 35

U.S.C. 102(e) as being anticipated by GILLIS et al. (US Publication No. 2003/0069541).

Gillis discloses a delivery system having first and second catheters 60 protruding from a multiple opening cannula 10 and a therapy device (50 and hub) that couples to the first and second catheters. Gillis discloses that the use of replenishment ports can be used to refill the delivery device for injection of additional drug [0008, 0126]. Fig. 4. The openings are capable of directing the catheters outwardly along a distinct predetermined trajectory because the openings are distinct (side by side) and predetermined (existing before the catheters are directed through).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 80, 81, 82, 83, 85, 86, 89, 90, 103, 106, and 107 are rejected under 35

U.S.C. 103(a) as being unpatentable over HOWARD, III (US Patent No. 6,129,685) in view of McGuckin et al. (US Patent No. 6,425,887). Howard discloses a delivery system with first and second catheters extending through a cannula from a reservoir/pump unit to deliver a drug where the pump supplies liquid medication as shown in figs. 25 and 30. Howard further discloses a replenishment port that is capable of being replenished by a hypodermic needle (col. 42, ll. 52-65). Howard, III does not show catheters extending

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from plurality of openings near the distal end of the cannula with each opening capable of directing a catheter outwardly along a predetermined trajectory. McGuckin discloses catheters extending from plurality of openings near the distal end of the cannula with each opening capable of directing a catheter outwardly along a predetermined trajectory (fig. 17). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of McGuckin in the system of Howard, III to treat different multiple areas of a patient and achieve a wider dispersion of delivered drug (see McGuckin col. 4, ll. 55-63).

Claims 84 and 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over HOWARD, III and McGuckin as applied to claims 80 and 103 above and further in view of ELSBERRY et al. (US Patent No. 5,711,316). Howard also discloses that the drug delivery pump can be controlled by a processor at a variable rate (col. 42, ll. 55-63). Howard and McGuckin do not disclose a sensor indicative of treated condition. Elsberry discloses a sensor indicative of treated condition to facilitate the delivery of the correct dosing of drug for treating a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Elsberry in the system of Howard to appropriately administer medication to treat a patient.

Claims 91, 92, 95, 96, 97, 98, 99, 100, 101, 104, and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over HOWARD, III and McGuckin as applied to claims 80 and 103 above and further in view of COSGROVE, Jr. et al. (US Patent No. 4,533,346). Howard, III and McGuckin disclose the claimed invention except for reading a parameter and level of signal to control liquid infusion rate, adjusting rate, and exceeding a maximum setting value results in indicative output. Cosgrove discloses an

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interfaced control scheme used in the prior art that adjusts a setting of infusion rates based on multiple analog signal levels based on the drug or physiological parameters (col. 3, line 55 - col. 5, line 62). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Cosgrove in the system of Howard, III and McGuckin in order to achieve precise control of drug delivery to a patient. It would have been obvious to one of ordinary skill in the art at the time of the invention to use alarms and telemetry in the process control scheme in order to alert the user when maximum or dangerous levels are exceeded to provide a better level of control and to use telemetry to enable remote control settings to be established.

Claim 94 is rejected under 35 U.S.C. 103(a) as being unpatentable over HOWARD, III and McGuckin and COSGROVE, Jr. et al. as applied to claim 92 above further in view of ABBOTT et al. (US Patent No. Re. 36386). Howard, III, McGuckin, and Cosgrove disclose the claimed invention except for resetting a timer when a parameter is changed. Abbott teaches resetting a timer when a parameter associated the flow rate is changed. (see para. (d) of claim 31). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Abbott in the system of Howard, III, McGuckin, and Cosgrove in order to obtain additional flow information concerning drug delivery parameters to more precisely control the drug delivery profile to the patient.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 80, 81, 82, 83, 85, 86, 89, 103, and 107 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 5, 23, and 24 of U.S. Patent No. 6,353,762 in view of GILLIS or IMRAN (US Patent No. 5,964,796). Patent '762 recites a delivery system having a cannula and plurality of openings to direct a catheter in a distinct predetermined trajectory, first and second catheters to deliver a liquid agent. Patent '762 does not recite a device that stores liquid agent and is coupled to the first and second catheters. Gillis and Imran each teach a device that stores liquid agent and is coupled to the first and second catheters (figs. 4, 7 respectively)

Response to Arguments

Applicant generally argues that the rejections under 112(1) should be withdrawn because there is support in other patents, incorporated by reference. Applicant does not

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provide support for the amendments. In their last response received 1/26/06, Applicant gives citations to references incorporated by reference that still do not provide support for the amendments. There is no support given for first and second catheters and catheter ports, as claimed in claim 85. Applicant reference to figs. 4-8, 10A, and 11 do not show this plurality.

Applicant states that support for at least one catheter port coupled to first and second catheter where the delivery system is configured to deliver at least two drugs is found at pg. 22, ll. 1-3 of the specification. Applicant states that support for infusion rate through first and second catheters with parameter and signal level is found in Elsberry, col. 7, ll. 49-53. Applicant states that support for using parameters and settings to control liquid infusion is found in Duggan, col. 5, l 1 - col. 6, l. 2. Applicant states that support for sensor in the proximity of liquid delivery is at Elsberry c4, ll. 1-42. No support for these amendments are found at these locations in the specification or references.

Applicant states that "outwardly" means directed out from the central axis. The examiner does not agree because the term "outwardly" was not defined in the specification as originally filed. The term is not viewed as narrowly as Applicant's arguments that it is directed from the central axis. Outwardly could be along the central axis if away from the device.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can

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usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
15 April 2006



MICHAEL J. HAYES
PRIMARY EXAMINER